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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,334	12/30/2004	Mitsuru Maeda	030685-042	8952

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/500,334

Applicant(s)

MAEDA ET AL.

Examiner

Traviss C. McIntosh

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 8 and 9 is/are allowed.
- 6) ☒ Claim(s) 2-7 and 10-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action***Information Disclosure Statement***

The information disclosure statement filed June 28, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted that none of the cited foreign patent documents have been received.

Claim Objections

Claims 3-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 3 and 4 depend from claim 2 which is drawn to a composition comprising 2-O-(β -D-glucopyranosyl) ascorbic acid. Claims 3 and 4 state that the 2-O-(β -D-glucopyranosyl) ascorbic acid is extracted from a plant of the family *Solanaceae* or *Lycium genuse* respectively. However, it is of no patentable import as to where the compound to be used in the composition is obtained from, and one of skill in the art would understand that 2-O-(β -D-glucopyranosyl) ascorbic acid derived from one plant is the same as 2-O-(β -D-glucopyranosyl) ascorbic acid derived from another plant.

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Applicant is advised that should claim 2 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the limitations of where the 2-O-(β -D-glucopyranosyl) ascorbic acid compound is produced is of no patentable import to the composition as claimed in claim 14, and as such, the composition of claim 14 is seen to be a duplicate to the composition of claim 2, as the only thing required is 2-O-(β -D-glucopyranosyl) ascorbic acid to be included therein.

Applicant is advised that should claim 2 be found allowable, claims 18-20 and 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The intended use as set forth in the preambles of claims 18-20 and 22 are of no patentable import to the compositions as claimed. The only thing required for the compositions is to include 2-O-(β -D-glucopyranosyl) ascorbic acid, and as such, claims 2, 18, 19, 20 and 22 are seen to be the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2-7, 10-15, and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to a composition comprising 2-O-(β -D-glucopyranosyl) ascorbic acid, but is silent to any other agents to be included therein. Compositions require more than one agent to be a composition, otherwise they are considered compounds. Adding an additional agent for which there is support founded in the disclosure as originally filed would obviate the instant rejection (i.e., a carrier, excipient, diluent, etc.). Claims 3, 4, 14, 18, 19, 20, 21, and 22 are rejected for the same reasons.

Claim 5 is indefinite wherein the claim is drawn to a method of producing 2-O-(β -D-glucopyranosyl) ascorbic acid from extraction from a plant, but the claim does not include any methodological steps which can be practiced. Methods of making compounds must include the steps necessary to perform the process.

Claims 6 and 7 depend from claim 5 and fail to add any methodological steps to the method of claim 5, and thus are rejected for the same reasons as claim 5 above.

Claims 10-13 are drawn to methods of producing 2-O-(β -D-glucopyranosyl) ascorbic acid, but fail to set forth any methodological steps to be used in the process. Methods of making compounds must include the steps necessary to perform the process.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 14, and 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Yagi et al. (EP 0 919 218 A1).

Claims 2-4, 14, and 18-22 are drawn to compositions comprising 2-O-(β -D-glucopyranosyl) ascorbic acid as set forth supra.

Yagi et al. disclose compositions comprising extracts of *Solanaceae* which are used for the same purpose as the compositions as claimed. While the source of the active agent and the intended use of the active agent has no patentable import to the compositions as claimed as set forth supra, it is noted that Yagi et al. disclose compositions of the same plant extracts used for the same purpose, and the examiner believes that the compositions of Yagi et al. must have inherently comprised the agent as disclosed in the instant application. As such, absent evidence to the contrary, claims 2-4, 14, and 18-22 are seen to be anticipated by Yagi et al.

Claims 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen (US 6,238,672 B1).

Claim 16 is drawn to a food containing 2-O-(β -D-glucopyranosyl) ascorbic acid. Claim 17 provides the food is vitamin C fortified.

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Chen disclose foods which comprise lycium fruit and cactus fruit (see examples 4, 9, 34 and 39). The cactus fruit is taught to comprise vitamin C, thus, the food of Chen must inherently comprise 2-O-(β -D-glucopyranosyl) ascorbic acid and they also added cactus fruit which comprises vitamin C, and thus inherently discloses the invention as claimed in claims 16 and 17 of the instant application.

Allowable Subject Matter

Claims 1, 8, and 9 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest the compounds of claims 1, 8, and 9 of the instant application. The prior art teaches of 2-O-(α -D-glucopyranosyl) ascorbic acid (note the alpha conformation) as vitamin C prodrugs (see US 5,407,812), but also teaches that β -derivatives cannot be decomposed in the body and are therefor not useful (see Japanese unexamined patent publication HEI no. 3-13599). As such, one of skill in the art would not have expected the β -derivatives to have efficacy as therapeutic agents.

Conclusion

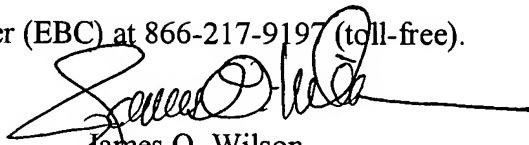
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh
October 14, 2005



James O. Wilson
Supervisory Patent Examiner
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